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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,822	10/02/2000	David A. Estell	GC527C2	3611

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EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	16

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
677,822	ESTELL et al
Examiner	Group Art Unit
SAUNDERS	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 10/4/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1, 4-10, 29-30 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1, 4-5, 7, 9-10, 29-30 is/are rejected.

☑ Claim(s) 6, 8 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10, 12

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Revi w, PTO-948

☐ Intervi w Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Oth r _____

Office Acti n Summary

Applicant's election without traverse of Group I (claims 1, 4-10 and 29-30) in paper No. 14(filed 10/0/02) is acknowledged.

Claims 1, 4-10 and 29-30 are pending and under examination.

The disclosure is objected to because of the following informalities: at specification page 1, the Cross-Reference to Related Applications section fails to refer to several related applications, for which applicant has claimed benefit in the declaration.

At page 15, line 19 the applicant has referred to an "R factor" without providing the formula therefore, as was provided in earliest application 09/060,872.

Appropriate correction is required.

Applicant is advised that should claim 7 be found allowable, claim 30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 9 and 10 "said polypeptide of interest and said homologue combined" is unclear, because nothing in base claim 8 has been recited as "combined". Note, that the phrase could be understood as reciting that the variant has at least one (or two) less

T-cell epitopes than the sum of the total number of epitopes of the polypeptide of interest and the total number of epitopes in homolog. It is not believed that this is what applicant intends.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 9-10 and 29 are rejected under 35 U.S.C. 101 because base claim 1 requires that the polypeptide have its T-cell epitope(s) altered such that a greater immunogenic response is obtained than would be obtained with a polypeptide having an unaltered T-cell epitope.

On the other hand dependent claims 9-10 require that the T-cell epitope(s) be eliminated. This elimination would be expected to provide an altered protein, which would induce a lesser, not a greater, immunogenic response. In deed the embodiment recited in claims 9-10 is presented in the disclosure as a way of reducing the allergenicity of a protein, not as a way of enhancing the immunogenicity thereof. Applicant has thus failed to disclose a protein having the alteration(s) set forth in claims 9-10 that would have any operative utility for providing a protein having the characteristics required for the protein of base claim 1.

Regarding claim 29, it is considered that applicant's disclosure has taught that "therapeutic proteins" (e.g. antibodies, lymphokines, growth factors, clot "busters" or clotting factors) should be rendered less, not more, immunogenic. Applicant has thus

failed to disclose any utility for a therapeutic protein, which has been rendered more immunogenic.

Claims 9-10 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant did not have possession of any proteins which have been altered by the elimination of one or more T-cell epitopes, as required by claims 9-10, and which also have a greater immunogenicity than the unaltered protein, as required by base claim 1.

In deed applicant's disclosure teaches that proteins having one or more T-cell epitopes eliminated would be less, not more, immunogenic than the unaltered protein. Also applicant did not disclose any "therapeutic protein" with increased immunogenicity.

Claims 9-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not enabled the provision of a protein, which has been altered to be more immunogenic than the unaltered protein by virtue of eliminating one or more epitopes, as required by claims 9 and 10.

Applicant's disclosure has taught that such alteration would decrease, not increase the immunogenicity of the protein. Thus one would be required to conduct undue experimentation to obtain any protein having greater immunogenicity as a result of eliminating T-cell epitopes.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless-
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 7 and 29 are rejected under 35 U.S.C. 102 (a) as being anticipated by Landry (WO 99/06061).

Landry shows altered proteins, which are modified at a T-cell epitope by virtue of insertion (usually N-terminally adjacent thereto, or partially overlapping the N-terminal) of an unstable (i.e. flexible) peptide segment. This insertion is consistent with the language of instant claim 1. It is also consistent with instant claim 30 because, in the embodiment in which the inserted sequence overlaps the N-terminus of the epitope, there would be substitutions within the epitope. Note also paragraph-spanning pages 11-12.

Applicant is referred to Landry at pages 5, 7, 11-12, 32 and 40-43, for example, for disclosures of altered full-length proteins.

Dependent claim 4 is rejected, since Landry teaches vaccines (page 32).

Claim 5 is included because gp 120 (exemplified at pages 40-43) is a protein from an infections virus, which is "exogenous" to an infected individual.

Claim 7 is included, since insertions taught by Landry encompass substitution (page 12).

Claim 29, though believed to be inconsistent with the recitation of a "greater" immunogenic response in base claim 1 (see utility and description rejections supra), is considered anticipated, since a recombinant vaccine can be considered a therapeutic protein, in the broadest since of the term "therapeutic".

Claims, 1, 4, 7 and 30 are rejected under 35 U.S.C. 102 (b) as being anticipated by Mouritsen et al. (WO 95/05849).

Mouritsen et al. disclose immunogenic forms of self-proteins (e.g. cytokines listed in the Para. Spanning pages 7-8), in which residues within the self-protein have been substituted with residues from a foreign (i.e. heterologous) T-cell epitope. These modified proteins are more immunogenic than the unmodified self-protein.

The language of claims 1 and 30 is sufficiently broad to encompass what is taught by Mouritsen et al. For example, nothing in either claim requires that the "T-cell epitope" of line 1 be the one, which has been altered in lines 2-4.

On attached copies of form PTO-1449 non-initialed references were not found by the examiner and have not been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday 8 am - 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. The fax phone numbers

for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

David a Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644

Saunders/T.G.D.
January 2, 2003